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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,305	12/20/2001	Tyrone L. Hardy	70012-36-CIP	4390

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EXAMINER

QADERI, RUNA S

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 04/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,305

Applicant(s)

HARDY ET AL.

Examiner

Runa S. Qaderi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 13-16 and 19-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Weber et al.

Weber et al. figures 9 and 11 clearly teach a continuous array of coupled fiducials (35) and (43), respectively, on the localizing catheter. Figures 9 and 11 clearly demonstrate the one or more imaging localization fiducials as taught by the applicant. One or more waveforms selected from the group of sine or cosine is taught in figures 9 and 11 of Weber et al. The fiducial pattern as claimed is shown in figures as well.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4, 6, 7, 9, 10, 12, 13-17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. in view of Wessels.

Miller teaches a method and apparatus of providing whole body localization. The localization is provided by custom mold to the entire body, posterior and anterior, figure 2. The patent further teaches radiopaque markers on the base or shell (18) of the apparatus as taught by the applicant. The radiopaque markers are arranged on a grid as shown in figure 1. The grid of radiopaque markers of Miller et al. is the continuous array of coupled fiducials as taught by the applicant. The radiopaque markers are used for registration on the x-rays. The whole body mold of Miller et al. is reusable for use in repeated radiation therapy.

The Miller et al. reference does not explicitly recite an alignment of the plane of the base with x-ray device. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have provided an apparatus and method wherein the frame need not orthogonally align within a scanning device because the invention of Miller et al. does not preclude from an available scanning orientation of the frame. Therefore one would have been motivated to provide for such scanning

orientation because it allows for the equivalent function of registering a position via fiducials within an image.

Miller et al. does not teach the specific fiducial arrangement as taught by the applicant. Wessels et al. teaches various fiducial array patterns that are used to better register positions in a cross-section or uniquely identify each cross-section, figure 1(a) and 1(b) and column 4. The fiducial arrangement shown in figure 1(a) of Wessels is interpreted as the waveform as taught by the applicant. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have incorporated the waveform of coupled fiducials of Wessels into the system of Miller et al. because it allows for a uniquely identifying each cross sectional image as taught by Wessels. The identification of each cross section allows for better registration of position within the image and therefore a more efficient therapeutic procedure. In addition it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have provided the waveform selected from the group consisting of a $\pi/2$ horizontal linked sine or cosine wave fiducial pattern because the Wessels patent clearly teaches that any shape would be apparent to one skilled in the art.

Claims 2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. in view of Wessels as applied to claims 1 and 7 above, and further in view of Phillips.

Miller et al. in view of Wessels does not teach said mold selected from the group consisting of a vacuum molds and polyurethane foam molds and anterior mold

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comprising a thermoplastic mold. Phillips et al. teaches using polyurethane and thermoplastics as cast materials used to make surgical supports, column 3 lines 33-35. It would have been obvious for a person of ordinary skill in the art at the time the invention was made to use polyurethane and thermoplastics because it is a well known alternative casting material in the art.

Claims 5, 11, 18, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. in view of Wessels as applied to claims 1, 7, 13, and 19, respectively, above, and further in view of Kormos.

Miller et al. in view of Wessels does not explicitly teach quality assurance markers placed in opposing pairs at predetermined positions along axis of the frame. Kormos et al. teaches a providing quality assurance markers placed in opposing pairs at predetermined positions along axis of the frame, column 3 and 4. It would have been obvious for a person of ordinary skill in the art at the time the invention was made to affix quality assurance markers as taught by Kormos et al. into the system of Miller et al. in view of Wessels because it allows for a more efficient stereotactic surgical procedure. Incorporation of additional fiducials is obvious when providing for an improved position registration. Further in would have been obvious to provide for opposing pairs at predetermined positions along axis of the frame because it provides an identical position of the fiducial markers during subsequent surgical procedures.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Runa S. Qaderi whose telephone number is (703) 308-8155. The examiner can normally be reached on Mon-Fri 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 746-7289 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

RSQ

RSQ
April 3, 2003



Marvin M. Lateef
Supervisory Patent Examiner
Group 3700